(a) Each serial shall meet the applicable general requirements provided in § 113.450.

(b) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested using the two-stage test provided in this section.

(1) In the first stage, each of 40 Swiss mice, each weighing 16 to 20 grams, shall be injected subcutaneously with 0.1 ml of product (dried product shall be rehydrated according to label directions). Twenty-four hours postinjection, the injected mice and 10 additional mice designated controls shall be challenged subcutaneously with the same culture of *Erysipelothrix rhusiopathiae.*

(2) If less than eight of the 10 controls die from erysipelas within 7 days post-challenge, the test is invalid. All dead mice shall be examined to determine if the cause of death was *Erysipelothrix rhusiopathiae* infection.

(3) The mice injected with product shall be observed for 10 days postchallenge and all deaths recorded. The second stage shall be required when 7–10 of the mice injected with product die in the first stage. The second stage shall be conducted in a manner identical to the first stage.

(4) The results of the test shall be evaluated according to the following table:

Stage	Number of vaccinates	Cumulative number of vaccinates	Cumulative total number of deaths for a satisfactory test	Cumulative total number of deaths for an unsatisfactory test
1	40	40	6 or less	11 or more.
2	40	80	12 or less	13 or more.

[39 FR 16859, May 10, 1974. Redesignated at 39 FR 25463, July 11, 1974, as amended at 40 FR 20067, May 8, 1975; 40 FR 23989, June 4, 1975. Redesignated at 55 FR 35561, Aug. 31, 1990; 61 FR 51776, Oct. 4, 1996; 64 FR 43045, Aug. 9, 1999]

§ 113.453 [Reserved]

§ 113.454 Clostridium Perfringens Type C Antitoxin.

Clostridium Perfringens Type C Antitoxin is a specific antibody product containing antibodies directed against the toxin of *Clostridium perfringens* Type C. Each serial shall be tested as provided in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) Each serial shall meet the applicable general requirements provided in § 113.450.

(b) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested using the toxin-neutralization test for Beta Antitoxin provided in this section. Dried products shall be rehydrated according to label directions.

(1) When used in this test, the following words and terms shall mean:

(i) *International antitoxin unit.* (I.U.) That quantity of Beta Antitoxin which reacts with L_0 and L_+ doses of Standard Toxin according to their definitions.

(ii) *L_0dose.* The largest quantity of toxin which can be mixed with one unit of Standard Antitoxin and not cause sickness or death in injected mice.

(iii) *L_+dose.* The smallest quantity of toxin which can be mixed with one unit of Standard Antitoxin and cause death in at least 80 percent of injected mice.

(iv) *Standard antitoxin.* The Beta Antitoxin preparation which has been standardized as to antitoxin unitage on the basis of the International *Clostridium perfringens* Beta Antitoxin Standard and which is either supplied by or acceptable to Animal and Plant Health Inspection Service. The antitoxin unit value shall be stated on the label.

(v) *Standard toxin.* The Beta toxin preparation which is supplied by or is acceptable to Animal and Plant Health Inspection Service.

(vi) *Diluent.* The solution used to make proper dilutions prescribed in this test. Such solution shall be made by dissolving 1 gram of peptone and 0.25 gram of sodium chloride in each 100 ml of distilled water; adjusting the pH to 7.2; autoclaving at 250 °F. for 25 minutes; and storing at 4 °C. until used.